

SOMANETICS CORRESTORE PERICARDIAL PATCH 510(k) PREMARKET NOTIFICATION

NOV 21 2001

Appendix J

510(k) Summary

Trade Name: CorRestore™ Patch K011487
Common Name: Processed Bovine Pericardial Patch
Establishment Information: Somanetics Corporation
 1653 East Maple Road
 Troy, MI 48083
 Phone: (248) 689-3050
 Fax: (248) 689-4272
Contact Person: Ronald A. Widman, Vice President of Medical Affairs
Classification: Class II, Panel 74 DXZ

Product Description:

The CorRestore Patch is an oval tissue patch made from glutaraldehyde fixed bovine pericardium. It is intended to be used as an intracardiac patch for cardiac reconstruction and repair. It is identical to other marketed bovine pericardium patches except that it incorporates an integral suture bolster (also made of fixed bovine pericardium) in the shape of an oval ring and is packaged with accessories needed for cardiac repair and reconstruction. The CorRestore Patch comes as a kit including a patch, suture strip (1.4 x 16 cm), and 20 pledgets, all manufactured from processed bovine pericardium. Each size can be ordered with or without a set of the various sutures needed for implantation. To assist the surgeon in determining the appropriate size, a separate disposable sizer kit is offered.

The CorRestore Patch comes in three sizes:

Part Number (with sutures)	Part Number (without sutures)	Product
1.5P2S	1.5P2	1.5 x 2 cm* CorRestore Patch
2P3S	2P3	2 x 3 cm* CorRestore Patch
3P4S	3P4	3 x 4 cm* CorRestore Patch

*Sizes refer to inside dimensions of suture ring; actual sizes are larger

A separate sizer kit is available to determine the appropriate size patch to implant:
 CRPS CorRestore Patch Sizer Set

Substantial Equivalence:

The CorRestore patch is equivalent in size, shape, and material, manufacturing processes, sterilization, packaging, instructions and intended use to other patches already marketed. The specific intended use, for cardiac repair and reconstruction, is an exact subset of the general intended use of the predicate devices. In vitro tests were utilized to evaluate the effect of the addition of the suture ring to the patch and results demonstrate that there are no new questions of safety and/or effectiveness. Therefore, the CorRestore Patch is substantially equivalent to the predicate devices:

Supple Peri-guard, K921895, Bio-Vascular, Inc.
 Vasu-Guard, K942010, Bio-vascular, Inc.
 Glycar Pericardial Patch, K963967, Glycar, Inc.
 Hancock Pericardial Patch, K830863, Extracorporeal



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2001

Mr. Ronald A. Widman
Vice President, Medical Affairs
Somanetics Corporation
1653 East Maple Road
Troy, MI 48083-4208

Re: K011487
Trade Name: CorRestore™ Patch
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac Patch or Pledget
Regulatory Class: Class II (two)
Product Code: DXZ
Dated: August 27, 2001
Received: August 28, 2001

Dear Mr. Widman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

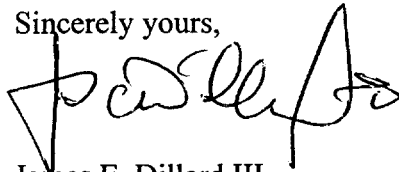
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "J. E. Dillard III", written over a horizontal line.

James E. Dillard III

Director

Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K011487

Device Name: CorRestore™ Patch Processed Bovine Pericardial Patch

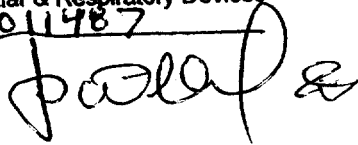
Indications For Use:

The CorRestore™ patch is intended for use during cardiac surgical procedures as an intracardiac patch for cardiac reconstruction and repair.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011487

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Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)